

Serial No.: 09/329,002
Docket No.: ECC-5062CIP2
Amendment After FINAL dated July 2, 2004
Responsive to Office Action of February 13, 2004

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

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Listing of claims:

1. (Currently amended) A multiple lumen access system for use in providing an entry port into the human body for selectively introducing medical devices therethrough and for providing auxiliary access into the body, the system including a multiple lumen access device comprising:
- an outer tube which has a distal end for introduction into the body and a proximal end;
- a device lumen defined within the outer tube, the device lumen having a distal end and a proximal end, wherein medical devices may be passed through the device lumen;
- an auxiliary lumen defined within the outer tube and separately from the device lumen, the auxiliary lumen having a distal end and a proximal end; and
- a flexible wall located within the outer tube having a distal end and a proximal end and opposite sides, wherein one side of the wall partly defines the device lumen and the other side of the wall partly defines the auxiliary lumen, the wall being sufficiently flexible to be movable from a first position, where the device lumen at the particular location has a first cross-sectional area, to multiple flexed positions, where the device lumen at the particular location has corresponding multiple cross-sectional areas which are greater than or less than the first cross-sectional area of the device lumen; and
- a junction housing having a proximal end and a distal end to which the proximal end of the outer tube connects, the junction housing including a main channel in fluid communication with the device lumen and an auxiliary channel in fluid communication with the auxiliary lumen, the main channel and auxiliary channel diverging from each other

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to be non-intersecting in the junction housing,

wherein the outer tube is relatively stiff in relation to the flexible wall to facilitate introduction of the outer tube into a human body.

5 2. (Original) The multiple lumen access system of claim 1 further comprising a device lumen valve adjacent the proximal end of the device lumen to provide sealing of the device lumen when medical devices are both present and absent from the device lumen.

10 3. (Previously presented) The multiple lumen access system of claim 1 further comprising a fluid reservoir connected to the proximal end of the auxiliary lumen.

15 4. (Currently amended) The multiple lumen access system of claim 1 wherein the junction housing is made of a soft, flexible material further comprising a junction housing having a proximal end and a distal end to which the proximal end of the outer tube connects, the junction housing including a main channel in fluid communication with the device lumen and an auxiliary channel in fluid communication with the auxiliary lumen, the main channel and auxiliary channel diverging from each other to be non-intersecting in the junction housing.

20 5. (Currently amended) The multiple lumen access system of claim 1 [4] further comprising a device lumen valve to provide sealing of the device lumen when medical devices are both present and absent from the device lumen, wherein the device lumen valve is provided as part of the junction housing and is in fluid communication with the main channel.

25 6. (Original) The multiple lumen access system of claim 5 further including a device channel in the junction housing formed at an angle with the main channel and terminating at an internal end in fluid communication with the main channel, the device lumen valve being positioned at an external end of the device channel so that medical devices may be inserted therethrough and enter the main channel at an angle.

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7. (Previously presented) A multiple lumen access system of claim 6 wherein the main channel extends from the distal end of the junction housing and opens at the proximal end of the junction housing enabling introduction of fluids therethrough to the main channel.

8. (Original) A multiple lumen access system according to claim 5 wherein the device lumen valve is molded separately from the junction housing of a material more rigid than the junction housing and is assembled with the multiple lumen access device by insertion in a cavity formed in the junction housing.

9. (Original) A multiple lumen access system according to claim 8 further including a device channel in the junction housing formed at an angle with the main channel and terminating at an internal end in fluid communication with the main channel, the device lumen valve being positioned in the cavity at an external end of the device channel so that medical devices may be inserted therethrough and enter the main channel at an angle.

10. (Previously presented) A multiple lumen access system according to claim 9 wherein the main channel extends from the distal end of the junction housing and opens at the proximal end of the junction housing enabling introduction of fluids therethrough to the main channel.

11. (Original) The multiple lumen access system of claim 5, wherein the device lumen valve has a contact face with at least one groove, and further comprising:

a contamination shield adapter having a contact face with at least one lug such that the lug mates with the groove when the adapter engages with the device lumen valve and provides a tactile feel to an operator when the adapter is properly engaged with the device lumen valve, the adapter being suitable for connecting a contamination shield to the device lumen valve.

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12. (Withdrawn) A multiple lumen access system according to claim 1 [4] wherein the main channel and auxiliary channel are oriented substantially coplanar so that the junction housing is substantially flat, and further including an extension tube extending from the proximal end of the junction housing and in fluid communication with the main channel wherein a device lumen valve is connected to the extension tube to therefore be in fluid communication with the main channel.

13. (Withdrawn) A multiple lumen access system according to claim 12 further including a side port in the device lumen valve enabling infusion of fluids to the extension tube and main channel.

14. (Withdrawn) A multiple lumen access system according to claim 12 further including mating threaded connectors between the device lumen valve and the extension tube enabling easy removal of the device lumen valve.

15. (Withdrawn) A multiple lumen access system according to claim 12 further including a second extension tube extending from the proximal end of the junction housing and in fluid communication with the auxiliary channel, and an auxiliary lumen valve connected to the second extension tube to therefore be in fluid communication with the auxiliary lumen.

16. (Withdrawn) The multiple lumen access system of claim 12 [14] further comprising a luer connector on the device lumen valve and an infusion syringe having a mating luer connector.

17. (Previously presented) The multiple lumen access system of claim 1 wherein two auxiliary lumens are located within the outer tube of the multiple lumen access device.

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18. (Original) The multiple lumen access system of claim 17 wherein the two auxiliary lumens are of different sizes.

19. (Withdrawn) The multiple lumen access system of claim 17 wherein one of the two auxiliary lumens is located between the other auxiliary lumen and the device lumen.

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20. (Original) The multiple lumen access system of claim 17 wherein the distal ends of the two auxiliary lumens are located at different locations between the proximal and distal ends of the outer tube.

21. (Previously presented) The multiple lumen access system of claim 1 wherein the auxiliary lumen has a maximum cross-section formed when the flexible wall is flexed away from the auxiliary lumen as far as possible, and the multiple lumen access device further includes an outlet for the auxiliary lumen formed in the outer tube, the outlet having an area that is greater than or equal to the maximum auxiliary lumen cross-section.

22. (Previously presented) The multiple lumen access system of claim 1 wherein there are two of the flexible walls that together form an inner tube within the outer tube.

23. (Previously presented) The multiple lumen access system of claim 22 wherein the inner tube has a distal end and a proximal end and an exterior surface and an interior surface, wherein the interior surface defines the device lumen, and wherein there are two of the auxiliary lumens located between the exterior surface of the inner tube and an interior surface of the outer tube.

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24. (Original) The multiple lumen access system of claim 23 wherein the inner tube is connected to the interior surface of the outer tube at two locations to delineate the two auxiliary lumens.

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25. (Withdrawn) The multiple lumen access system of claim 1 wherein at least one spacer rib is located on an interior surface of the outer tube for maintaining a space between the outer tube and the flexible wall.

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26. (Previously presented) The multiple lumen access system of claim 1 wherein the outer tube is made from a different material than the flexible wall.

27. (Original) The multiple lumen access system of claim 1 further comprising a
10 medical device located within the device lumen.

28. (Original) The multiple lumen access system of claim 1 wherein the flexible wall is constructed from a material and with a shape that moves from the relaxed position toward the flexed positions upon a pressure differential between the auxiliary lumen and the device lumen, the
15 movement being toward the device lumen, and wherein a displacement response curve of the flexible wall is non-linear such that the wall resists substantial movement from small pressure differentials.

29. (Original) The multiple lumen access system of claim 28 wherein the flexible wall
20 has a variable thickness with areas of weakness in bending created at thinner portions so that when a device is present in the device lumen the wall contacts the device substantially along a line of contact to facilitate sliding of the device within the device lumen.

30. (Currently amended) A multiple lumen access system for use in providing an
25 entry port into the human body for selectively introducing medical devices therethrough and for providing auxiliary access into the body, the system including a multiple lumen access device comprising:

a sheath defining a device lumen and at least one auxiliary lumen, both having a

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distal end and a proximal end, wherein medical devices may be passed through the device lumen; and

a proximal junction housing made of a ~~soft~~ flexible material softer than the material of the sheath having a proximal end and a distal end to which the proximal end of the sheath connects, the junction housing including a main channel in fluid communication with the device lumen and an auxiliary channel in fluid communication with the auxiliary lumen, the main channel and auxiliary channel diverging from each other to be non-intersecting in the junction housing, the junction housing further defining a cavity on the proximal end in fluid communication with the main channel.

31. (Original) A multiple lumen access system according to claim 30 further including a device lumen valve attached to the junction housing so as to be in fluid communication with the device lumen of the sheath.

32. (Original) A multiple lumen access system according to claim 31 wherein the device lumen valve is molded separately from the junction housing of a material more rigid than the junction housing and assembled with the multiple lumen access device by insertion in the cavity formed in the junction housing.

33. (Previously presented) A multiple lumen access system according to claim 31 further including a device channel in the junction housing formed at an angle with the main channel and terminating at an internal end in fluid communication with the main channel, the cavity being located at an outermost end of the device channel, the device lumen valve being positioned in the cavity so that medical devices may be inserted therethrough and enter the main channel at an angle.

34. (Original) A multiple lumen access system according to claim 31 wherein the device lumen valve comprises a multi-component valve insert with a two-part rigid outer housing

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and at least one elastomeric inner valve member within the housing.

35. (Original) A multiple lumen access system according to claim 34 wherein the two-part rigid outer housing includes a portion forming an outermost opening and having internal
5 threads for coupling with adapters for introducing medical devices.

36. (Original) A multiple lumen access system according to claim 34 including an elastomeric duckbill valve and an elastomeric wiper gasket within the housing.

10 37. (Previously presented) A multiple lumen access system according to claim 30 further including a flexible wall located within the sheath and having a distal end and a proximal end and opposite sides, wherein one side of the wall partly defines the device lumen and the other side of the wall partly defines the auxiliary lumen, the wall being sufficiently flexible to be movable from a relaxed position, where the device lumen at a particular location along its length has a first
15 cross-sectional area, to multiple flexed positions, where the device lumen at the particular location has corresponding multiple cross-sectional areas which are greater than or less than the first cross-sectional area of the device lumen, and wherein at the particular location the sheath has a cross-sectional area that remains substantially unchanged and any of the cross-sectional areas of the device lumen does not exceed the cross-sectional area of the sheath.

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Claims 38-59 (canceled).

60. (Currently amended) A method for selectively introducing medical devices into a human body through a single entry port and for providing simultaneous auxiliary fluid access
25 into the body, comprising:

providing a multiple lumen access device comprising:

an elongated body which has a distal end for introduction into the body and a proximal end;

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a device lumen through which medical devices may be passed defined within the elongated body, the device lumen having a distal end and a proximal end;

an auxiliary lumen defined within the elongated body and separately from the device lumen, the auxiliary lumen having a distal end and a proximal end; and

5 a flexible wall located within the elongated body having a distal end and a proximal end and opposite sides, wherein one side of the wall partly defines the device lumen and the other side of the wall partly defines the auxiliary lumen, the wall being sufficiently flexible to be movable from a first position, where the device lumen at the particular location has a first cross-sectional area, to multiple flexed positions, where the
10 device lumen at the particular location has corresponding multiple cross-sectional areas which are greater than or less than the first cross-sectional area of the device lumen, wherein the elongated body is relatively stiff in relation to the flexible wall to facilitate introduction of the elongated body into a human body;

15 introducing the multiple lumen access device into the body with the distal ends of the device lumen and the auxiliary lumen being positioned within a vasculature of the human body; and

flowing a medical solution through the auxiliary lumen into the vasculature in the absence of a device in the device lumen to move the flexible wall from the first position to one of the flexed positions;

20 inserting a medical device through the device lumen into the vasculature; and
flowing a medical solution through the auxiliary lumen into the vasculature with a device present in the device lumen.

61. (Canceled)

25 62. (Previously presented) The method of claim 60 further comprising the step of providing the multiple lumen access device with a fluid reservoir connected to the proximal end of the auxiliary lumen.

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63. (Previously presented) The method of claim 60 further comprising the step of providing the multiple lumen access device with a device lumen valve to provide sealing of the device lumen when medical devices are both present and absent from the device lumen.

64. (Previously presented) The method of claim 63 further comprising the step of providing the multiple lumen access device with a junction housing having a proximal end and a distal end to which the proximal end of the elongated body connects, the junction housing including a main channel in fluid communication with the device lumen and an auxiliary channel in fluid communication with the auxiliary lumen, the main channel and auxiliary channel diverging from each other to be non-intersecting in the junction housing.

65. (Original) The method of claim 64 wherein the device lumen valve is provided as part of the junction housing and is in fluid communication with the main channel.

66. (Original) The method of claim 65 further comprising the step of providing the multiple lumen access device with a device channel in the junction housing formed at an angle with the main channel and terminating at an internal end in fluid communication with the main channel, the device lumen valve being positioned at an external end of the device channel so that medical devices may be inserted therethrough and enter the main channel at an angle.

67. (Previously presented) The method of claim 66 wherein the main channel extends from the distal end of the junction housing and opens at the proximal end of the junction housing enabling introduction of fluids therethrough to the main channel.

68. (Original) The method of claim 65 wherein the device lumen valve is molded separately from the junction housing of a material more rigid than the junction housing and is assembled with the multiple lumen access device by insertion in a cavity formed in the junction

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housing.

69. (Original) The method of claim 65 further comprising the step of providing the multiple lumen access device with a device channel in the junction housing formed at an angle with the main channel and terminating at an internal end in fluid communication with the main channel, the device lumen valve being positioned in the cavity at an external end of the device channel so that medical devices may be inserted therethrough and enter the main channel at an angle.

70. (Previously presented) The method of claim 69 wherein the main channel extends from the distal end of the junction housing and opens at the proximal end of the junction housing enabling introduction of fluids therethrough to the main channel.

71. (Withdrawn) The method of claim 64 wherein the main channel and auxiliary channel are oriented substantially coplanar so that the junction housing is substantially flat, and further including an extension tube extending from the proximal end of the junction housing and in fluid communication with the main channel wherein the device lumen valve is connected to the extension tube to therefore be in fluid communication with the main channel.

72. (Withdrawn) The method of claim 71 further comprising the step of providing the multiple lumen access device with a side port in the device lumen valve enabling infusion of fluids to the extension tube and main channel.

73. (Withdrawn) The method of claim 71 further comprising the step of providing the multiple lumen access device with mating threaded connectors between the device lumen valve and the extension tube enabling easy removal of the device lumen valve.

74. (Withdrawn) The method of claim 73 further comprising the step of providing the

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multiple lumen access device with a luer connector on the device lumen valve and an infusion syringe having a mating luer connector.

75. (Previously presented) The method of claim 60 wherein two auxiliary lumens are
5 located within the elongated body of the multiple lumen access device.

76. (Currently amended) The method of claim ~~75~~ 60 wherein the distal ends of the
two auxiliary lumens are located at different locations between the proximal and distal ends of
the elongated body.

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77. (Previously presented) The method of claim 60 wherein the multiple lumen access
device comprises an inner tube formed by two of the flexible walls located within the elongated
body, the inner tube having a distal end and a proximal end, and the inner tube having an exterior
surface and an interior surface wherein the interior surface defines the device lumen, and two
15 auxiliary lumens located between the exterior surface of the inner tube and an interior surface of
the elongated body.

78. (Original) The method of claim 77 wherein the inner tube is connected to the
interior surface of the elongated body at two locations to delineate the two auxiliary lumens.

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79. (Previously presented) The method of claim 60 wherein the elongated body is
made from a different material than the flexible wall.

80. (Original) The method of claim 60 further comprising the steps of:

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providing a device lumen valve adjacent the proximal end of the device lumen to
provide sealing of the device lumen when medical devices are both present and absent from
the device lumen, the device lumen valve having a contact face with at least one groove;
providing an adapter having a contact face with at least one lug such that the lug

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mates with the groove when the adapter engages with the device lumen valve and provides a tactile feel to an operator when the adapter is properly engaged with the device lumen valve; and

connecting a contamination shield to the adapter.

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Claims 81-87 (cancelled).